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Comparison of the Teno Fix Tendon Repair System and a standard suture repair in Zone II flexor tendon lacerations of the hand.

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2005	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2005	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/04/2011	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0013145917

Study information

Scientific Title

Study objectives
Is there a reduced rupture rate and improved outcome using the Teno Fix Tendon Repair System in comparison to a standard suture repair in zone II flexor tendon lacerations in the hand?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Injury, Occupational Diseases, Poisoning: Tendon lacerations

Interventions
Randomisation of adult patients with zone II flexor tendon lacerations to receive either the Teno Fix repair or standard suture repair. Assessment of outcomes by blinded, independent observer.

Added 29 July 2008: trial stopped in 2006 due to poor recruitment.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Tendon rupture rate and digital range of motion at 12 weeks post-repair.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2003

Completion date
01/09/2003

Reason abandoned (if study stopped)
Poor recruitment

Eligibility

Key inclusion criteria
Adult patients with acute Zone II flexor tendon lacerations in the hand.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
50

Key exclusion criteria
1. Adults above 60 yrs of age
2. Flexor tendon lacerations outside Zone 2
3. Complex injuries, eg crush, mutilation, skin loss, amputations, revascularisation
4. The presence of established infection in injured hand
5. Associated digital fractures
6. Delayed surgery
7. Severe intercurrent medical illness
8. Drugs, eg immunosuppressives, steroids, which can affect healing
9. Previous injuries to affected hand
10. Pre-existing arthritis in affected hand
11. Allergy to metals in the stainless steel suture of Teno Fix (chromium, copper, cobalt, nickel, iron)

Date of first enrolment
01/03/2003

Date of final enrolment

01/09/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Plastic Surgery
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Guy's and St. Thomas' NHS Foundation Trust (UK) Own account

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration